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APPLICATION NO.	F	ILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO
09/779,282		02/08/2001	James D. Holker	PD-0436	7532
23608	7590	06/30/2005		EXAMINER	
MEDTRONIC MINIMED INC. 18000 DEVONSHIRE STREET NORTHRIDGE, CA 91325-1219				MAIORINO, ROZ	
				ART UNIT	ART UNIT PAPER NUMBER
	,			3763	

DATE MAILED: 06/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Application No. Applicant(s)			$\boldsymbol{\varepsilon}$					
Examiner Roz Malorino The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. Edenations of this may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed If the period for reply specified above is less than thirty (30) days, a reply whithin the set of or reply specified above is less than thirty (30) days, a reply whithin the set of or reply specified above is less than thirty (30) days, a reply whithin the set of or reply specified above is less than thirty (30) days, a reply whithin the set of or reply with the set of extended period for reply will be period for reply within the set of extended above is less than thirty (30) days, a reply within the set that the period for reply will be considered timely. If the period for reply specified above is less than thirty (30) days, a reply within the set and the period by the Control of the reply within the set of extended period for reply will, by statute, cause the sapplication to become ABANDONED (30 U.S.C. § 133). Any reply scene the by the Office of the communication. Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 13). Any reply scene by the Office of the communication, even if timely filed, may reduce any service of the communication of the communication, even if timely filed, may reduce any service of the communication of the communication, even if timely filed, may reduce any service of the profit of the communication, even if timely filed, may reduce any service of the second profit of the communication, even if timely filed to file communication. 1) Responsive to communication is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11,		Application No.						
Roz Maiorino 3763 - The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION Estensions of time may be available under the provisions of 37 CFR 1.135(a). In no event, however, may a reply be timely filled after SIX (8) MONTH'S from the mailing date of this communication If the period for reply shift in the satisfact above is less than thit; (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely If NO period for reply shift in the soft on stended period for early within the statutory period will apply and will expire 3X (8) MONTH'S from the mailing date of this communication Failute to reply within the soft on stended period for early will be considered timely If NO period for reply shift in the soft or explored period for early will be a destinated above in the satisfaction cause the explanation (a) advanced and ANCHORDE (2) SLS. 2 \$135) Failute to reply within the soft or explored period for early will be shaded above in the communication Failute to reply within the soft or explored period or early will be considered timely Failute to reply within the soft or explored period on the properties. 1) □ Responsive to communication(s) filled on 13 April 2005. 2a) □ This action is FINAL - 2b) □ This action is non-final. 3) □ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) □ Claim(s) 1-13 and 89-91 is/are pending in the application. 4a) □ Claim(s) 1-13 and 89-91 is/are allowed □ Claim(s) 1-13 and 89-91 is/are explaced to be the communication. Application Papers 9) □ The		09/779,282	HOLKER ET AL.					
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A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be limely filled after SIX (6) MONTH'S from the mailing date of this communication. - If the period for reply specified above, his maximum statutory period will apply and will expire SIX (6) MONTH'S from the mailing date of this communication. - If the period for reply specified above, his maximum statutory period will apply and will expire SIX (6) MONTH'S from the mailing date of this communication of the period for reply specified above, his maximum statutory period will apply and will expire SIX (6) MONTH'S from the mailing date of this communication, and the period will apply and will expire SIX (6) MONTH'S from the mailing date of this communication, and the period will apply and will expire SIX (6) MONTH'S from the mailing date of this communication, and period will apply and will expire SIX (6) MONTH'S from the mailing date of this communication, and period will apply and will expire SIX (6) MONTH'S from the mailing date of this communication, and period will apply and will expire SIX (6) MONTH'S from the mailing date of this communication, and period will apply and will expire SIX (6) MONTH'S from the mailing date of this communication. - Apply received by the Office later than three months after the mailing date of this communication, and the period will apply and will expire SIX (6) MONTH'S from the mailing date of this communication. - The period for replace the mailing date of this communication, and the period will apply and will expire SIX (6) MONTH'S from the mailing date of this communication. - The period for replace the mailing date of this communication, and the period will apply and will expire SIX (6) MONTH'S from the mailing date of this communication. - The period for replace the mailing date of this communication. - The period for replace the period that the		Roz Maiorino	3763					
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3. Copies of the certified copies of the priority documents have been received in this National Stage								
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application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received.			ed					
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Attachment(s)	Attachment(s)	_						
1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Notice of Draftsperson's Patent Drawing Review (PTO-948) Paper No(s)/Mail Date.								
2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 5) Notice of Informal Patent Application (PTO-152) Cother:	3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08	3) 5) Notice of Informal F						

Application/Control Number: 09/779,282

Art Unit: 3763

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
- (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

1. Claims 1-13, 89-91 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent NO. 6360888 to McIvor et al.

McIvor teaches a sensor with a substrate with notches cut in the substrate to form a neck down region in the substrate and a sensor electrode formed from conductive layer

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wherein the notches cut in the substrate do not expose any sensor electrodes to analyses, further including a slotted needle having a slot. (figures 1-2, 13-15)

2. Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent NO. 4543958 to Cartmell .

Cartmell teaches a sensor with a substrate with notches cut in the substrate to form a neck down region in the substrate and a sensor electrode formed from conductive layer wherein the notches cut in the substrate do not expose any sensor electrodes to analyses.

3. Claims 1-13, 89-91 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent NO. 5390671 to Lord et al.

Lord teaches a sensor with a substrate with notches cut in the substrate to form a neck down region in the substrate and a sensor electrode formed from conductive layer wherein the notches cut in the substrate do not expose any sensor electrodes to analyses, further including a slotted needle having a slot.

4. Claims 1-3, 6-13, 89-91 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent NO. 5391250 to Cheney II et al.

Cheney teaches a sensor with a substrate with notches cut in the substrate to form a neck down region in the substrate and a sensor electrode formed from conductive layer wherein the notches cut in the substrate do not expose any sensor electrodes to analyses, further including a slotted needle having a slot.

5. Claims 1-3, 6-13, 89-91 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent NO. 6461496 to Feldman et al.

Feldman teaches a sensor with a substrate with notches cut in the substrate to form a neck down region in the substrate and a sensor electrode formed from conductive layer wherein the notches cut in the substrate do not expose any sensor electrodes to analyses, further including a slotted needle having a slot.

Double Patenting

6. Claims 1-13, 89-91 rejected under the judicially created doctrine of double patenting over claims 22-97 of U. S. Patent No. 6484045 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: the applicants claims are a broad version of the patent claims.

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application which matured into a patent. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

Response to Arguments

7. Applicant's arguments with respect to claims 1-3, 6-13, 89-90 are have been considered but are most in view of the new ground(s) of rejection.

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8. Applicant's arguments filed 4-13-20065 have been fully considered but they are not persuasive.

- a. Applicant alleges McIvor does not teach a notch however definition of a notch is "An indentation at the edge of a structure", which McIvor teaches.
- b. In response to applicant's arguments, the recitation implantable has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).
- c. In response to applicant's argument that implantable and non-necked region is adapted for placement within the body, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 312 F.2d 937, 939, 136 USPQ 458, 459 (CCPA 1963).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roz Maiorino whose telephone number is 571- 272-4960. The examiner can normally be reached on 9am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 703-308-2698. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RM

NICHOLAS D. LUCCHESI SUPERVISORY PATENT EXAMINER TECHNOLOGY CENTER 3700